

## REMARKS

Reconsideration of the subject application as amended herein is respectfully requested. The Examiner's detailed objections to the claims are appreciated. The claims have been reviewed and amended in response. If the Examiner believes that further changes are necessary he is cordially invited to contact the undersigned for an expeditious resolution.

The Examiner has rejected claims 1, 10, 38 and some of the claims dependent thereon as being anticipated by the Bardy reference or obvious over Bardy in combination with Nappholz '740. The Applicant respectfully traverses these rejections.

Briefly, the present application pertains to rate responsive pacemakers, and more particularly to a pacemaker wherein the pacing rate is controlled by a metabolic demand parameter, such as minute volume. Rate responsive pacemakers, per se, are not new. What the present inventor has discovered is that for optimal performance, the pacing rate should also be varied in synchronism with the respiration of the patient. The independent claims have been amended to recite this feature more clearly. More specifically, claim 1 now defines that the pacemaker includes an adjuster circuit which changes the metabolic rate cyclically. The result is an adjusted metabolic parameter which follows the respiration. Similarly claim 38 has been amended so that it now specifies 'adjusting said base pacing parameter by increasing and decreasing said base pacing parameter in synchronization with said respiration."

Claim 12 has been found allowable and its limitations, as well as the limitations of claim 11 have been incorporated into claim 10 and accordingly this claim is now in allowable condition. Regarding the rejection of claims 1 and 38, the Examiner takes the position that the Nappholz and Bardy references in combination teach the claimed invention. Nappholz merely teaches a rate responsive pacemaker and does not take respiration into consideration at all. Bardy is cited for teaching cardiac pacer with a respirator sensor and a controller. The Examiner points to col. 7 and Fig. 4B to support his view that this reference, alone, or in combination with Nappholz, teaches the present invention. It is respectfully submitted that this position is erroneous. Col. 7 of patent only alludes to the fact that physiological sensor is used to determine a metabolic parameter, and that this parameter may be derived either from an oxygen saturation sensor, a respiration sensor, or a physical activity sensor. (Col. 7, lines 34-43). No details are given of how the invention is implemented using the respiration sensor. In any event, this passage clearly indicates that Bardy contemplated using a single sensor. In the present invention two sensors are used, one for a metabolic demand, and a second for respiration. The claims (1 and 38) clearly recite that the first sensor is used to generate a metabolic demand parameter and a second sensor is used to generate a respiration indication. Thus the following major characteristics distinguish the present invention over the Bardy reference. First, Bardy uses only a single sensor at any given time while two sensors are used in the present invention. Bardy generates a parameter from the single sensor which is used to determine pacing. In the present invention, the first sensor is used to generate a basic parameter which is

then modified or adjusted using the output of the second parameter. In fact in a preferred embodiment, the metabolic demand parameter is adjusted by only a small amount. Third, the second parameter is used to adjust the metabolic demand cyclically or in synchronism with the respiration. There is nothing in Bardy to indicate this mode of operation.

Thus it is respectfully submitted that the subject application as claimed herein is patentably distinguishable and therefore it should be allowed.

Respectfully submitted,

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